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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,279	12/04/2001	Juan C. Colberg	PCI0862A	2249

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EXAMINER	
BERCH, MARK L	
ART UNIT	PAPER NUMBER

1624  
DATE MAILED: 09/27/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/006,279	COLBERG ET AL.	
	Examiner	Art Unit	
	Mark L. Berch	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-24 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1-24 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> .	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 7-20, rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "cycloalkyl" (e.g. at page 33, line 13) by a defective definition in the specification. Page 5, line 12 refers to 1-2 optional double bonds, which would not be a cycloalkyl but a cycloalkenyl.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11, 13-16, 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 92/01696.

The acylation process is set forth beginning at page 17, line 24. Note that in the reference, n is required to be zero. Note that  $\text{CO}_2\text{R}^3$  can be carboxy (or salt thereof), as set forth in e.g. the abstract. In the actual examples, acylation is done with the esters, e.g. examples 1 (step g), <sup>3</sup>2 (step h), 13 (step g), etc. Thus, the sole difference is that applicants use the acid (or salt), while the reference's specific examples use the esters.

But the page 17-18 text teaches that the acid can also be used. Applicants must show unexpected effects arising from the use of the acid rather than the ester. Specifics of solvent, catalyst, etc are present on page 18-22, e.g. page 22, lines 3 and 17 (the carbodiimide coupling agent of claims 14-15 is conventional, and is used in example 22). Hence, claims 1, 5-11, 13-16, 21-22 are obvious

With regard to claim 23-24, example 6 step d; example 7, step a; example 9, step a; example 14, step d; example 15, step d and others all teach the p-methoxybenzyl esters, while the claims have the p-nitrobenzyl ester. However, page 5, lines 14-15 teach this exact equivalence. Clearly, one of ordinary skill in the art would understand that either can be used, since both are named on these two lines. By the same reasoning, example 7 renders claim 3 obvious; the claim removes the p-nitrobenzyl group, the example removes the p-methoxybenzyl ester. Likewise, example 1, step h removes the t-butyl group, but again, page 5 teaches that equivalence. See also examples 18-19, 22-23 step b, and many others. Removing either group would be obvious, because page 5 teaches that any of these groups can be used. With regard to claim 4, which has acylation done on a salt, that specific feature is mentioned at page 17, line 26. As for claim 20, these two solvents are listed at page 20, lines 24 and 26.

Claim 2 has deprotecting using a salt starting material. This is seen in example 17, step i; example 1, step h; example 2, step i; example 5, step b; example 12, step h; and others, where the salt is formed first with HCl.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 703-308-4718. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708-308-1235.



Mark L. Berch  
Primary Examiner  
Art Unit 1624

September 26, 2002